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EXAMINER
RAWLINGS, STEPHEN L

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1642	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/676,340	Applicant(s) SUBJECK ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2002 and 28 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *11-15,17-21,24-32 and 35-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,16-18,22,23,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The election with traverse and the supplemental election with traverse, which were filed February 27, 2002 in Paper No. 8 and March 28, 2002 in Paper No. 9, respectively, are acknowledged and have been entered.

2. Claims 1-45 are pending in the application. Claims 11-15, 19-21, 24-32, and 35-45 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

3. Claims 1-10, 16-18, 22, 23, 33, and 34, insofar as the claims are drawn to a pharmaceutical composition and method for using said composition, wherein said composition comprises hsp110 and an immunogenic polypeptide associated with cancer, are currently under prosecution.

Election/Restrictions

4. Applicants' election with traverse of Group 1, claims 1-10, 16-18, 22, 23, 33, and 34, in Paper No. 8 is acknowledged. In addition, Applicants' election with traverse of species in Paper No. 9 is acknowledged. The traversal is on the grounds that the subject matter of the claims is dependent and closely related. Furthermore, Applicants assert that the claimed subject matter is linked by a common inventive concept. Therefore, Applicants contend that the restriction requirement is improper and examining the claimed subject matter, as a whole would not constitute a substantial burden.

Applicants' grounds of traversal have been carefully considered but have not been found persuasive. The inventions are distinct for the reasons already of record and because the search required for examination of each is not coextensive with any one of the others, examination of more than one of the inventions would constitute a serious burden. Furthermore, although some of the claimed subject matter may have

originated from a single common inventive concept, it is nonetheless divergent, as evidenced by the need to perform separate and distinct searches of the distinct subject matter claimed in the application. Accordingly, the restriction requirement is deemed proper and is therefore made FINAL.

Claim Objections

5. Claims 1-10, 16-18, 22, 23, 33, and 34 are objected to because of the following informalities:

Claims 1-10, 16-18, 22, 23, 33, and 34 are objected to because claims 1-3, 9, and 22 recite a reference to a non-elected invention. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7, 16, 33, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is vague and indefinite because claim 7 recites the term "members of the hsp70, hsp90, grp78 and grp94 stress family protein families". Recitation of the term renders the claim vague and indefinite because it is unclear to which proteins the claim refers, as it is unclear which proteins are members of the hsp70, hsp90, grp78, and grp94 families. Furthermore, presently the claim would encompass any member of the stress protein families that has yet to be discovered or categorized as such, and Applicants' could not have contemplated the use of such proteins, besides which have not been adequately described in the specification. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. Amending claim 7 to recite a list of the specific members of the stress protein families of which the claimed composition can comprise will more particularly point out and distinctly claim the subject matter that Applicants' regard as their invention and therefore

will obviate this ground of rejection. However, Applicants' are cautioned against the introduction of new matter.

Claim 16 is vague and indefinite because claim 16 recites the term "associated with". Recitation of the term renders the claim vague and indefinite because it is unclear how the claim requires the immunogenic polypeptide to be associated with a cancer. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Claims 33 and 34 are vague and indefinite because claims 33 and 34 recite the term "an effective amount". The phrase "effective amount" is indefinite when the claims fail to state the function that is to be achieved. See *In re Frederiksen & Nielsen*, 213 F 2d 547, 102 USPQ 35 (CCPA 1954). Moreover, recitation of the term renders the claim vague and indefinite because it is unclear to which effect the claim refers and therefore it could not be determined what amount of the pharmaceutical composition would necessarily be administered to the subject so that this effect is achieved in practicing the claimed method. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. Amending claims 33 and 34 to recite, for example, the phrase "an effective amount of the pharmaceutical composition of claim 16 to elicit an antitumor immune response in said subject" can obviate this ground of rejection.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international

application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1, 2, 4-10, 16-18, 23, 33, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,891,432-A.

US Patent No. 5,891,432-A ('432) teaches methods for producing and using a cellular vaccine to treat or prevent cancer in a subject. More specifically, '432 teaches a pharmaceutical composition comprising a genetically engineered cell that expresses a fusion protein comprising an immunomodulatory molecule fused to a disease-associated antigen or immunogenic epitope thereof (abstract). '432 teaches that the immunomodulatory molecule can be a heat shock protein; moreover, '432 teaches that the immunomodulatory molecule can be hsp110 (paragraph bridging columns 6 and 7). '432 teaches that the disease-associated antigen or immunogenic epitope thereof can be a tumor-associated antigen, namely HER-2/Neu or a peptide derived therefrom (column 14, lines 49-58; column 14, lines 22-30), and '432 provides two examples of such in Table 3 (columns 15 and 16). '432 teaches that the pharmaceutical composition can further comprise a second immunomodulatory molecule in membrane-bound or soluble form, which in turn, can be fused to a second disease-associated antigen or immunogenic peptide thereof (column 18, lines 33-38). Accordingly, the second immunomodulatory molecule can be any other protein that is "induced by stress-causing condition such as heat shock or glucose deprivation", including in particular, hsp110, hsp90, hsp70, hsp60, hsp25, hsp20, and hsp8.5 (paragraph bridging columns 6 and 7). '432 teaches that an expression vector encoding the fusion protein can be introduced into a cell to produce such a vaccine; the expression vector can comprise a first polynucleotide sequence encoding hsp110 operably linked to a second polynucleotide

encoding HER-2/Neu or a peptide derived therefrom (paragraph bridging columns 12 and 13). '432 teaches the cellular vaccine can comprise an appropriate adjuvant and can be administered with a pharmacologically acceptable solution. Although '432 does not explicitly teach that the heat shock protein complexes formed in the genetically engineered cells can comprise hsp110, hsp70, and hsp25, the ability of hsp110 to associate with a denatured or improperly folded polypeptide, hsp70, and hsp25 is an inherent property of the protein or proteins. Therefore, the pharmaceutical composition of the prior art is deemed the same as the pharmaceutical composition of claim 8, absent a showing of any difference. The Office, however, does not have the facilities for examining and comparing Applicants' product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural, and functional characteristics of the claimed product or would not function identically as the claimed pharmaceutical composition. In the absence of evidence to the contrary, the burden is upon the Applicants to prove that the claimed pharmaceutical composition are functionally different than those taught by the prior art and to establish patentable differences.

11. Claims 1-3, 5, 6, 8, 16-18, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,747,332-A.

US Patent No. 5,747,332-A ('332) teaches a method for producing a pharmaceutical composition that can be administered to a subject in an effective amount to treat or prevent cancer in the subject. More specifically, '332 teaches a method for isolating or synthesizing heat shock protein complexes comprising hsp110 associated by a non-covalent interaction with an immunogenic polypeptide (claims 1, 9, 13, and 21). The process of '332 can comprise a step in which the solution containing the heat shock protein complexes or the components thereof at a temperature of 37 to 50 °C (claims 4 and 16; column 3, lines 1-7). '332 teaches that the heat shock protein complexes or the components thereof can be derived from tumor cells (column 4, Examples 1 and 2) or alternatively, cells infected with an infectious agent (column 2, lines 54 –67). In addition, '332 teaches methods for isolating or synthesizing heat shock

protein complexes comprising hsp60, hsp65, rubisco binding protein, TCP-1, GroEL/GroES, Mif4, TCP-α, TCP-β, hsp104, hsp105, hsp110, DnaK, Ssa, Ssb, Ssc, hsp70, Grp75, Grp78 (BiP), hsp90, gp96, and grp94 (claims 8-11 and 20-23). Although '332 does not explicitly teach that the isolated heat shock protein can comprise hsp110, hsp70, and hsp25, the ability of hsp110 to associate with a denatured or improperly folded polypeptide, hsp70, and hsp25 is an inherent property of the protein or proteins. Therefore, the pharmaceutical composition of produced by the method of the prior art is deemed the same as the pharmaceutical composition of claim 8, absent a showing of any difference. Similarly, '332 does not explicitly disclose that the heat shock protein complexes derived from tumor cell lysates can comprise the intracellular domain of her-2/neu or a peptide fragment thereof, but nevertheless it is an inherent property of a tumor cell that expresses her-2/neu to do so, and an inherent property of the heat shock proteins to form a complex with misfolded her-2/neu polypeptides. Therefore, for example, if a breast tumor cell over-expressing her-2/neu were used as the source of the tumor cell lysate, the pharmaceutical composition produced by the methodology disclosed by '332 would comprise a heat shock protein complex comprising an immunogenic polypeptide comprising the intracellular domain of her-2/neu or a peptide fragment thereof. Accordingly, the pharmaceutical composition produced by the method of the prior art is deemed the same as the pharmaceutical composition of claim 18, absent a showing of any difference. Again, however, the Office does not have the facilities for examining and comparing Applicants' product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural, and functional characteristics of the claimed product or would not function identically as the claimed pharmaceutical composition. In the absence of evidence to the contrary, the burden is upon the Applicants to prove that the claimed pharmaceutical composition are functionally different than those taught by the prior art and to establish patentable differences.

12. Claims 1-3, 5, 6, 8, and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,066,716-A.

US Patent No. 6,066,716-A ('716) teaches a method for producing a pharmaceutical composition that can be administered to a subject in an effective amount to treat or prevent cancer in the subject. More specifically, '716 teaches a method for isolating or synthesizing heat shock protein complexes comprising hsp110 associated by a non-covalent interaction with an immunogenic polypeptide (claims 7). '716 teaches that the heat shock protein complexes or the components thereof can be derived from tumor cells (column 4, Examples 1 and 2) or alternatively, cells infected with an infectious agent (paragraph bridging columns 2 and 3). In addition, '716 teaches methods for isolating or synthesizing heat shock protein complexes comprising hsp60, hsp65, rubisco binding protein, TCP-1, GroEL/GroES, Mif4, TCP-α, TCP-β, hsp104, hsp105, hsp110, DnaK, Ssa, Ssb, Ssc, Grp75, and Grp78 (BiP) (claims 1, 7, 13, 19, and 25). '716 teaches that the heat shock protein complexes is not necessarily a naturally occurring product, as the heat shock protein complexes prepared by the disclosed methodology can comprise a heat shock protein derived from a first cell, individual, organism, or species and an immunogenic peptide derived from a second cell, individual, organism, or species (claims 8-12). Although '716 does not explicitly teach that the isolated heat shock protein can comprise hsp110, hsp70, and hsp25, the ability of hsp110 to associate with a denatured or improperly folded polypeptide, hsp70, and hsp25 is an inherent property of the protein or proteins. Therefore, the pharmaceutical composition of produced by the method of the prior art is deemed the same as the pharmaceutical composition of claim 8, absent a showing of any difference. Similarly, '716 does not explicitly disclose that the heat shock protein complexes derived from tumor cell lysates can comprise the intracellular domain of her-2/neu or a peptide fragment thereof, but nevertheless it is an inherent property of a tumor cell that expresses her-2/neu to do so, and an inherent property of the heat shock proteins to form a complex with misfolded her-2/neu polypeptides. Therefore, for example, if a breast tumor cell over-expressing her-2/neu were used as the source of the tumor cell lysate, the pharmaceutical composition produced by the methodology disclosed by '332 would comprise a heat shock protein complex comprising an immunogenic polypeptide comprising the intracellular domain of her-2/neu or a peptide fragment thereof.

Accordingly, the pharmaceutical composition produced by the method of the prior art is deemed the same as the pharmaceutical composition of claim 18, absent a showing of any difference. Again, however, the Office does not have the facilities for examining and comparing Applicants' product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural, and functional characteristics of the claimed product or would not function identically as the claimed pharmaceutical composition. In the absence of evidence to the contrary, the burden is upon the Applicants to prove that the claimed pharmaceutical composition are functionally different than those taught by the prior art and to establish patentable differences.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-10, 16-18, 22, 23, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Nos. 5,747,332-A, 5,981,706-A, and 6,066,716-A in view of Disis, et al (*Clinical Cancer Research* **5**: 1289-1297, 1999), in further view of US Patent No. 6,322,790-B1, and in still further view of US Patent Nos. 5,891,432-A, 6,331,299-B1, and Lee-Yoon, et al (*Journal of Biological Chemistry* **270**: 15725-15733, 1995).

US Patent Nos. 5,891,432-A ('432), 5,747,332-A ('332), and 6,066,716-A ('716) teach that which is set forth in the corresponding 35 USC § 102(b) rejections above.

US Patent No. 5,981,706-A ('706) teaches a method for producing a pharmaceutical composition comprising a heat shock protein complex, wherein said heat shock protein complex comprises hsp110 that is associated with an immunogenic

polypeptide by a non-covalent interaction (column 6, Example). More specifically, '706 teaches a method for isolating or synthesizing heat shock protein complexes comprising hsp110 associated by a non-covalent interaction with an immunogenic polypeptide (claims 11). '706 also teaches an apparatus that can be used to synthesize heat shock protein complexes comprising hsp110 (claim 21). '706 teaches that the heat shock protein complexes or the components thereof can be derived from tumor cells (column 2, lines 12-25). In addition, '706 teaches methods for isolating or synthesizing heat shock protein complexes comprising hsp60, hsp65, rubisco binding protein, TCP-1, GroEL/GroES, Mif4, TCP-α, TCP-β, hsp104, hsp105, hsp110, DnaK, Ssa, Ssb, Ssc, hsp70, Grp75, Grp78 (BiP), hsp90, gp96, and grp94 (claims 10-13). '716 teaches that the heat shock protein complexes prepared by the disclosed methodology can comprise a heat shock protein derived from a first individual or species and an immunogenic peptide derived from a second individual or species (claims 14-16).

However, US Patent Nos. '332, '706, and '716 do not explicitly teach that the heat shock protein complex can comprise a fusion protein, or that the heat shock complex can comprise hsp110 associated with hsp70 and hsp25. In addition, '332, '706, and '716 do not explicitly teach that the pharmaceutical complex can further comprise a second member of the heat shock protein or glucose-regulated protein families. '332, '706, and '716 do not explicitly teach that the immunogenic polypeptide associated with the heat shock protein can be a tumor-associated antigen derived from, or comprising the intracellular domain of her-2/neu protein. Finally, '332, '706, and '716 do not explicitly teach that the pharmaceutical composition can comprise a nucleic acid molecule comprising a polynucleotide sequence encoding a fusion protein composed of hsp110 and an immunogenic polypeptide.

Disis, et al teach that peptide-based vaccines that comprise a fragment of the HER-2/neu oncogenic protein, which can be used to immunize patients diagnosed with breast or ovarian cancer to elicit a tumor-specific immune response in the immunized patients (abstract). Disis, teach that the vaccine can be formulated with peptides derived from the extracellular or the intracellular domains of HER-2/neu (page 1292, Figure 1; page 1293, Figure 2).

US Patent No. 6,322,790-B1 ('790) teaches methods for eliciting an immune response in an individual diagnosed with or at risk for developing primary or metastatic cancer (abstract). The method of '790 comprises administering to an individual a first composition comprising a first purified heat shock protein complex that comprises a first heat shock protein associated non-covalently with an immunogenic polypeptide. The method further comprises administering to the individual a second composition comprising a second purified heat shock protein complex that comprises a second heat shock protein associated also non-covalently with an immunogenic polypeptide (claim 1). The first and second heat shock protein complexes can comprise hsp70, hsp90, gp96, or a mixture of two or more of these heat shock proteins (claims 2-4), but '790 discloses that any heat stress protein complex can be used (column 10, lines 22-32). The pharmaceutical composition or compositions administered to the individual can also comprise an adjuvant (claim 12). The heat shock protein complexes can be derived from tumor cells (claims 23 and 27) or alternatively, from cells infected with an infectious agent (claim 26). '790 discloses that as an alternative, pharmaceutical composition comprising antigen-processing cells sensitized with the heat shock protein complexes can be used (columns 23 and 24).

US Patent No. 6,331,299-B1 ('299) teaches the use of heat shock protein complexes to stimulate an antitumor immunological response in an individual diagnosed with cancer (column 1, lines 14-18). '299 teaches that the method comprises collecting tumor cells from an individual, introducing a nucleic acid molecule into the isolated cells, and administering the recombinant tumor cells to the individual (claim 1). According to the disclosure set forth in '299, the nucleic acid molecule can comprise a polynucleotide sequence encoding a heat shock protein (column 2, lines 38-42), and includes as an example of such, BiP (grp78), hsp/hsc70, gp96 (grp94), hsp60, hsp40, and hsp90 (column 1, lines 26-32).

Lee-Yoon, et al teach the polynucleotide sequence of a nucleic acid molecule encoding hsp110.

In view of the teachings of Disis, et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the

methods and apparatus set forth in US Patent Nos. '332, '706, and '716 to produce and use a pharmaceutical composition comprising a heat shock protein complex, wherein said heat shock protein complex comprises hsp110 associated with an immunogenic peptide derived from the intracellular domain of HER-2/Neu, because Disis, et al teach that immunogenic peptides derived from the intracellular domain of HER-2/Neu effectively stimulate an antitumor immune response in individuals immunized with a vaccine composed of the peptides. In further view of the teachings of US Patent '790, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced and used a pharmaceutical composition comprising two or more heat shock protein complexes, wherein said heat shock protein complexes comprise hsp110, hsp70, or other members of the hsp70, hsp90, grp78, or grp94 stress protein families, because '790 teaches that composition comprising a combination of two or more heat shock protein complexes can effectively elicit an antitumor immune response in an individual immunized with such a composition. In still further view of the teachings set forth in US Patent Nos. '432 and '299, and Lee-Yoon, et al, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have produced an pharmaceutical composition comprising a nucleic acid molecule comprising a polynucleotide sequence encoding a fusion protein, wherein said fusion protein comprises hsp110 and an immunogenic peptide derived from the intracellular domain of HER-2/Neu, because '432 and '299 teach that pharmaceutical compositions comprising recombinant cells expressing enforced levels of heat shock proteins or fusion proteins comprising heat shock proteins and immunological polypeptides can effectively elicit antitumor immune response in individuals immunized with such compositions. One of ordinary skill in the art, at the time the invention was made, would have been motivated to have done so, because there had been a long-felt need for a more effective method for treating and preventing cancers, such as breast and ovarian cancer, that over-express the HER-2/Neu oncogenic protein.

Conclusion

15. No claims are allowed.

16. The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure. Each additional reference teaches or suggests methods for producing and using pharmaceutical compositions comprising heat shock or glucose-regulated proteins.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
June 17, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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